

Drug and Medical Device Product Liability + Globalization = Potential Costly International Mass Tort Litigation

Q How can a drug and medical device company recognize when it may face a global issue?

David Ferrera: Not every litigation presents the potential for an *international* mass tort. A drug or medical device company may have a problem with a particular manufacturing lot that can be isolated to a particular market. By contrast, there are often global “signaling events” that can alert companies to the potential of an international mass tort, such as an international recall of a product, foreign media or government entities “stirring the pot,” or poor clinical results presented in a foreign public journal or medical meeting.

Q What are some indicators of the scope of the global litigation?

DF: There are several factors that determine the reach of global litigation, including the number of claims filed, the availability of class actions, unique adverse event trends, varying levels of publicity, and jurisdictions with aggressive government agencies. For example, U.S. companies may be surprised to learn that some EU countries, such as Italy and Germany, allow a claimant to report a matter of alleged harm to the local criminal authorities, who will investigate and potentially prosecute local operating company executives.

Q What is different about using fact and expert witnesses in an international mass tort?

DF: After a company has its attorney team in place, the next step is to quickly identify who—and where—will be the principal fact and expert witnesses. Company fact witnesses from foreign jurisdictions need significant coaching by U.S. counsel to understand our very unique legal system. In addition, the rules of using expert witnesses are frequently different abroad—experts may be advocates or neutral court advisors. In the U.S., a company will hire the experts and expect them to be advocates. By contrast, in some international jurisdictions, the court hires the experts, and expects them to be impartial. These issues may affect both with whom the company consults and their interactions with attorneys.

Q What are some unique trial and settlement issues in the age of globalization?

DF: Companies should develop cooperation networks with overseas lawyers. They will discuss what worked and what did not at trial, share witnesses and strategies, and adapt accordingly for future litigations. Some countries, such as Australia, offer all direct exam by lengthy affidavit. This creates a treasure trove of detailed testimony with exhibits that lawyers can mine for cross-examination in the U.S.

A company can have a trial in the U.S. first that will have an impact on pending litigation in a foreign jurisdiction, or vice-versa. In an age where 98% of all cases settle, a mass settlement in one jurisdiction can impact litigation in the remaining jurisdictions. With the prevalence of the Internet, the instant a settlement program is made public, it is broadcast around the world. U.S. settlement payments tend to be larger than those made overseas, and foreign litigants may demand “equal payment” and create a ruckus in the press about a big U.S. company treating U.S. clients better than local ones. Not every settlement scheme works in every country, and simply copying the procedural details of a U.S. mass tort settlement program may not work elsewhere.

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David L. Ferrera, Partner, Chair, Product Liability and Toxic Tort Litigation Practice Group

617.439.2247
dferrera@nutter.com

David L. Ferrera is a partner in the Litigation Department and chair of the Product Liability and Toxic Tort Litigation practice group. He is a member of the firm’s Executive Committee.

David focuses his practice in the drug and medical device industries, where he works frequently with in-house and outside counsel in Canada, EMEA, and ASPAC on litigation issues affecting multinational clients.

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Press Contact:

Heather Merton
Senior Communications Manager

617.439.2166
hmerton@nutter.com

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